UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LEON D. BOROCHOFF, On Behalf of Himself and All Others Similarly Situated, Plaintiff, vs. GLAXOSMITHKLINE PLC, et al., Defendants.	Civil Action No. 1:07-cv-05574-LLS CLASS ACTION MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT

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STATUTES, RULES AND REGULATIONS

Lead Plaintiff Avon Pension Fund, Administered by Bath & North East Somerset Council ("Avon Pension Fund") and Plaintiffs Plumbers & Steamfitters Local 773 Pension Fund ("Plumbers & Steamfitters Local 773") and Plumbers' Union Local No. 12 Pension Fund ("Plumbers' Union Local No. 12") (collectively, "Plaintiffs") respectfully submit this memorandum of law in opposition to Defendants' GlaxoSmithKline PLC ("Glaxo," "GSK" or the "Company"), Jean-Pierre Garnier ("Garnier"), David Stout ("Stout"), Julian Heslop ("Heslop") and Simon Bicknell ("Bicknell")[1] motion to dismiss the Amended Complaint (the "AC"), dated November 13, 2007.

I. PRELIMINARY STATEMENT

This is a consolidated federal securities fraud class action brought on behalf of all persons who purchased or otherwise acquired Glaxo's American Depository Shares ("ADSs") and ordinary shares between October 27, 2005 and May 21, 2007 inclusive (the "Class Period"), alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.

In 1999, Glaxo obtained approval to market Avandia for the treatment of type 2 diabetes. Since that time, Glaxo has actively sought to obscure and conceal the material fact that the use of Avandia has been linked to the increased risk of heart attack. As revealed in a recent Congressional investigation (detailed further herein), in 1999, Glaxo intimidated an independent scientist, Dr. John Buse ("Buse") who had criticized Avandia by suggesting that it caused an increased risk of heart attack. According to the Senate Committee Report (defined, *infra*, at p. 8), Glaxo was successful in silencing Buse by going to his superiors and threatening litigation. Thus, the truth about Avandia was concealed from the market.

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[1] Defendants Garnier, Stout, Heslop and Bicknell are collectively referred to as the "Individual Defendants."

Several years later, starting in 2005, Glaxo completed two analyses of data based on 42 clinical trials of Avandia (the "Meta-Analyses"). The Meta-Analyses concluded that the use of Avandia presented an increased risk of heart attack. Despite the importance of this information, Glaxo did not disclose the conclusions from its internal analyses to the public and investors, despite making positive statements about Avandia and its material contribution to the Company's financial results. Ultimately, almost 18 months after Glaxo completed its Meta-Analyses, the market learned that there were "potential safety issues" with Avandia, *i.e.*, that certain studies had linked the use of Avandia to the increased risk of heart attack. The price of Glaxo securities causally declined in response to this adverse information. Prior to the disclosure of this information, certain of the Individual Defendants and other Glaxo insiders collectively sold more than 500,000 shares of their personally-held Glaxo securities, generating proceeds of $27.5 million.

Faced with these simple and straightforward allegations, Defendants substitute heft for substance. In this regard, Defendants introduce reams of extraneous facts and arguments in an effort to convince the Court that they have complied with their obligations under the securities laws. Now, however, is not the appropriate juncture for Defendants' explanations and justifications – that is for summary judgment. At this stage, the Court is required to accept the allegations of the AC as true, draw all reasonable inferences in Plaintiffs' favor and determine if Plaintiffs have sufficiently alleged a claim.

Under this standard, the AC easily passes muster. Contrary to Defendants' assertions, it is well settled that positive statements about a topic, even if literally true, can be materially false and misleading and actionable under the federal securities laws by failing to disclose then-known material adverse facts about that topic. In other words, when you choose to speak on a topic, you

must do so fully and truthfully. Here, Defendants' positive statements about Avandia created a duty to disclose the internal studies indicating that the use of Avandia increased the risk of heart attack.

In an effort to sidestep this basic principle of securities law, Defendants waste mountains of paper arguing that Glaxo's internal studies were not material information because the studies did not provide "a reason to believe that the future viability of the product" (Avandia) was in jeopardy. Def. Mem. at 35, 46.[2] Putting aside the issue of whether Defendants' argument is improperly predicated on facts and documents from outside the four corners of the AC, Defendants' primary authorities, *In re Carter-Wallace, Inc.*, 150 F.3d 153, 157 (2d Cir. 1998) ("*Carter-Wallace I*") and *In re Bayer AG Sec. Litig.*, No. 03-cv-1546 WHP, 2004 WL 2190357 (S.D.N.Y. Sept. 30, 2004) ("*Bayer*"), do not support their position. *Carter-Wallace I* and *Bayer* do not hold that a Company may conceal adverse material facts about a drug until the adverse information indicates that the future viability of a drug is in jeopardy, as Defendants contend. Rather, in those opinions, the Courts looked at when the issuer was aware of, or recklessly disregarded, a direct link between the drug and the alleged safety issue. When the link was apparent, disclosure is required. Here, contrary to Defendants' protestations, Glaxo has admitted that based on its internal studies, it knew of the connection between Avandia and the increased risk of heart attacks and did not disclose this information to investors. In other words, Defendants have acknowledged what was missing in *Carter-Wallace I* and *Bayer* – the link between the drug and the undisclosed safety issue. This is enough to survive Defendants' motion to dismiss.

For the reasons stated herein, it is respectfully submitted that Defendants' motion to dismiss should be denied in its entirety.

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[2] "Def. Mem. at ___" refers to pages in Defendants' Memorandum of Law in Support of Defendants' Motion to Dismiss Amended Complaint, dated December 13, 2007.

II. STATEMENT OF FACTS

A. The Company and Avandia

Glaxo develops, produces and sells pharmaceuticals, over-the-counter (OTC) medicines, vaccines and health-related consumer products. ¶20.[3] The Company markets Avandia (rosiglitazone maleate) as a drug intended to help improve blood sugar control in type 2 diabetics. ¶21. Avandia was Glaxo's second best-selling drug in 2006, with global sales of $3.38 billion. ¶22.

In 1999, Avandia was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of type 2 diabetes. Type 2 diabetes is a life threatening disease that, according to the FDA as of June 2007, affects approximately 18 to 20 million Americans. Since its introduction, the labeling of Avandia has been altered several times, including the addition of a warning for the risk of congestive heart failure. ¶23.

B. Glaxo Fails to Disclose Internal Studies that Indicate that the Use of Avandia Causes Increased Risk of Heart Attack

Since Avandia was introduced to the market, there have been several studies conducted that assessed the efficacy, safety, side-effects, etc., of the drug. ¶¶25, 26, 29. The various studies included analyses of the potential risk of myocardial infarction and cardiovascular deaths (heart attacks) associated with the use of Avandia.

In September 2005, Glaxo finalized a meta-analysis it performed in connection with Avandia.[4] ¶25. Specifically, Glaxo performed a patient-level meta-analysis of safety data from 37

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[3] "¶___" refers to paragraphs in the Amended Complaint for Violation of the Federal Securities Laws, dated November 13, 2007.

[4] Defendants recharacterize what Plaintiffs described as the "First Meta-Analysis" and "Second Meta-Analysis" in their AC as the "Preliminary Meta-Analysis" and "Final Meta-Analysis." Def. Mem. at 17, n. 27. For the purposes of Defendants' motion and the corresponding briefing, Defendants' footnote raises a factual issue which cannot be resolved on this motion. That

clinical trials (the "Preliminary Meta-Analysis"). Glaxo's Preliminary Meta-Analysis showed an estimate of excess risk of ischemic cardiovascular events, *i.e.*, an increased risk of heart attack, associated with the use of Avandia. ¶25. Yet, despite possessing the data and results showing Avandia presented an increased risk of heart attacks, Defendants did not inform or disclose these findings to investors.

In January 2006, Glaxo initiated a second meta-analysis of Avandia (the "Final Meta-Analysis"). ¶26. The Final Meta-Analysis, comprised of a total of 42 clinical trials, incorporated additional studies that were completed following the Preliminary Meta-Analysis. ¶26. The results of Glaxo's Final Meta-Analysis were finalized in March 2006. The results of Glaxo's Final Meta-Analysis showed an excess risk of ischemic cardiovascular events associated with the use of Avandia that was ***even greater*** than the risk portrayed in the Preliminary Meta-Analysis. ¶26. *See* Def. Mem. at 18 ("The final meta-analysis results 'suggested an increased risk for myocardial ischemia.'"). Again, despite possessing the data and results showing Avandia presented an increased risk of heart attacks, Defendants did not disclose these findings to investors.

In August 2006, Glaxo supplied the FDA with its Meta-Analyses. ¶27. According to the FDA, Glaxo did not immediately release the data or findings from the Meta-Analyses pending its own comprehensive internal re-analysis of that data. ¶27.

Defendants have admitted that they were aware of the findings from the Meta-Analyses that Avandia exposed its users to an increased risk of heart attacks. In a July 9, 2007 article in *The Wall Street Journal*, Defendant Garnier admitted that the Company previously performed the Meta-

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said, in order to avoid confusion, Plaintiffs will use Defendants' defined terms for the meta-analyses in this memorandum and collectively refer to them as the "Meta-Analyses" (defined, *supra*, at 2) where appropriate.

Analyses and that he was aware that the results of the Meta-Analyses indicated that Avandia caused an increased risk of heart attack. ¶35. In the same article, Defendant Garnier acknowledged that Glaxo failed to adequately communicate the risks of Avandia. In this regard, Defendant Garnier was asked: "Has Glaxo done everything it could to study Avandia and communicate its risks to the public?" Defendant Garnier responded to that question with the following statement of admission: "We're not perfect. I'm sure. With 20-20 hindsight we could have done more." ¶35.[5]

C. Throughout the Class Period, Defendants Repeatedly Issued Positive Statements About Avandia, but Failed to Disclose the Internal Studies Linking Avandia to Increased Risk of Heart Attack

Throughout the Class Period, Defendants issued numerous statements regarding Glaxo's financial performance, directly tying Avandia to the financial strength, growth and continued success of the Company. Defendants also issued numerous statements regarding the efficacy and safety of Avandia. These statements were materially false and misleading because they failed to disclose Glaxo's internal studies – the Meta-Analyses – which showed a risk of heart attack linked to the use of Avandia. *See, e.g.*, ¶¶42-63.

D. The Market Learns that Avandia Has Been Linked to an Increased Risk of Heart Attack and the Price of Glaxo Securities Decline

On May 21, 2007, the truth relating to the risk of heart attack for Avandia users was revealed to the market. ¶64. On that date, Dr. Stephen Nissen's[6] meta-analysis of Avandia was published by the *New England Journal of Medicine* ("*NEJM*"). ¶66. Simply put, Dr. Nissen concluded that

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[5] A May 31, 2007 *The Wall Street Journal* article reported that in a letter published on the website of *The Lancet*, a medical journal, Glaxo's chief medical officer, Ronald Krall, wrote that the Company had found indications of increased risk of heart attacks associated with Avandia in its own previously-conducted Meta-Analyses of clinical studies of Avandia. ¶34.

[6] Dr. Nissen is the Chairman of the Department of Cardiovascular Medicine at the Cleveland Clinic.

patients taking Avandia are at an increased risk for heart attacks. ¶66.[7]

Also on May 21, 2007, the FDA issued a safety alert, which explicitly recognized an increased risk of heart attack through the use of Avandia. ¶65. According to the FDA's initial analysis of Glaxo's Meta-Analyses, the data expressed a significant concern regarding the excess risk of heart attacks in Avandia-treated patients. ¶65. The FDA's alert also specifically addressed the potential risks identified by its own pooled analysis of completed controlled clinical trials, which established a potentially significant increase in the risk of heart attack and heart-related deaths in patients taking Avandia. ¶65.

In response to these announcements, the price of Glaxo ADSs declined by $4.53 per ADS, or 7.8%, on unusually high trading volume. ¶67. Similarly, Glaxo's ordinary shares, which trade on the London Stock Exchange ("LSE"), dropped 74 pence per share. Glaxo's ADSs and ordinary shares continued to lose value as the impact of the negative publicity was digested by investors, eventually falling from $57.71 per ADS and 1464 pence per share to $53.18 per ADS and 1390 pence per share, respectively, on May 29, 2007. ¶67.

Analysts were also surprised by the disclosure that linked Avandia to an increased risk of heart attack and lowered their earnings estimates for the Company based on their view of the negative impact on Avandia sales. ¶37. For example, on June 7, 2007, Bear Stearns lowered its earnings per share estimates for Glaxo, stating: "In view of the risks to GSK's US Avandia franchise, we have reduced our Avandia forecasts." ¶38. Bear Stearns' June 7, 2007 report added that "Avandia's cardiovascular risk profile remains an overhang on the stock. . . ." ¶38. Shortly

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[7] Dr. Nissen's analysis was based on data derived from 42 controlled clinical trials. Notably, many (but not all) of the 42 controlled clinical trials utilized by Dr. Nissen were the same studies used by Glaxo in its Meta-Analyses. ¶32.

thereafter, on July 25, 2007, Bear Stearns downgraded Glaxo and wrote: "Since May 23, 2007, when Dr. Nissen's meta-analysis on Avandia's CV risk profile was published in the *NEJM*, GSK shares have come off 5.4% to reflect the expected earnings impact. We cut our Avandia sales projections on June 8, 2007. . . ."[8] ¶39.

E. New Information on Avandia and the Risk of Heart Attack

Subsequent to the filing of the AC, additional information came to light about Avandia and its connection to the increased risk of heart attack. Although Plaintiffs respectfully submit that the AC states a claim, these newly discovered facts could be included in an amended pleading should the Court deem it necessary.

1. Congressional Investigation Concludes that Glaxo Intimidated an Influential Doctor in Order to Silence His Concerns About Avandia and Its Negative Cardiovascular Effects

According to a November 2007 U.S. Senate Committee report by the Committee on Finance,[9] Glaxo was aware of (and apprehensive about) the link between Avandia and the risk of heart attacks ***as early as 1999***.[10] The Senate Committee Report found that in 1999, Dr. John Buse[11]

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[8] Prior to May 21, 2007 (and dating back to the beginning of the Class Period), not a single analyst report mentioned or discussed a meta-analysis performed in connection with Avandia. Clearly, the Preliminary Meta-Analysis and the Final Meta-Analysis that were performed by the Company were not part of the public realm and not yet part of the total mix of information available to shareholders concerning Glaxo.

[9] The United States Senate Committee on Finance (the "Committee"), as part of its jurisdiction over the country's Medicare and Medicaid Programs, is responsible to all Americans who receive healthcare coverage under those programs. That responsibility includes overseeing the administration of the programs. The Senate Committee Report (defined below) and corresponding investigation was prepared and conducted in connection with the Committee's described jurisdiction and responsibility.

[10] The Intimidation of Dr. John Buse and the Diabetes Drug Avandia, Committee Staff Report to the Chairman and Ranking Member United States Senate Committee on Finance, November 2007 (the "Senate Committee Report"). (Attached hereto as Exhibit A.)

expressed concerns regarding the cardiovascular risks – including heart attacks – associated with Avandia. Glaxo was not only knowledgeable about the link between Avandia and heart attacks, but, according to the Senate Committee Report, Defendants Garnier and Stout, as well as the then research chief for the Company (Tachi Yamada), were participants in a concerted effort to intimidate Dr. Buse and curb his endeavor to publicize Avandia's potential negative cardiovascular effects and dangerous side-effects (Senate Committee Report, p. 2, 4). Specifically, the Senate Committee Report confirmed that Glaxo stifled Dr. Buse by complaining to his superiors at the University of North Carolina, calling him a "renegade" and ultimately threatening him with the prospect of facing a lawsuit by one the largest pharmaceutical companies in the world.

Defendants publicly tried denouncing the accusations that they muffled Dr. Buse and covered up the risk of heart attacks tied to Avandia.[12] The Senate Committee Report countered Glaxo's attempted repudiation, stating that internal documents from the Company "contradicted that claim and reveal what appears to be an orchestrated plan to stifle the opinion of Dr. John Buse."[13] The Senate Committee Report even commented on the manner in which the Company continued its efforts to conceal the risk of heart attacks associated with Avandia, despite the Senate Committee's thorough investigation and findings: "GSK's behavior since the Committee first brought these allegations to light has been less than stellar. Instead of acknowledging the misdeed to investors,

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[11] Dr. Buse is a renowned diabetes expert and professor of medicine at the University of North Carolina.

[12] Anna Wilde Mathews and Jeanne Whalen, Diabetes Expert Raised Issue of Avandia Heart Risk in 2000, Wall St. J., May 24, 2007. (Attached hereto as Exhibit B.)

[13] The Senate Committee Report added: "According to documents provided to the Committee by, among others, GSK, and the University of North Carolina, it is apparent that the original allegations, regarding Dr. Buse and GSK's attempts at silencing him are true. . . ." (Senate Committee Report, p. 2.)

apologizing to patients, and pledging to change corporate behavior, GSK launched a public relations campaign of denial."

Regarding the (statistical) significance of the link between Avandia and the risk of heart attack, the Senate Committee Report accentuated that "[a]t a July 30, 2007, safety panel on Avandia, FDA scientists presented an analysis estimating that Avandia caused approximately ***83,000 excess heart attacks*** since coming on the market." [Emphasis added.][14]

2. Additional Study Linking Avandia to an Increased Risk of Heart Attack

On December 12, 2007, *The Journal of the American Medical Association* ("*JAMA*") published a study that was led by Clinical Evaluative Services in Toronto. The *JAMA* study concluded that "TZD treatment, primarily with rosiglitazone [Avandia], was associated with an increased risk of congestive heart failure, acute myocardial infarction, and mortality when compared with other combination oral hypoglycemic agent treatments."[15] Subsequent media coverage summarized the findings of the *JAMA* study and emphasized the statistical significance of the link between Avandia and the risk of heart attack, as follows:

- In an article dated December 12, 2007, *USA Today* reported that patients who took Avandia had a higher risk of heart attacks. Furthermore, the *USA Today* article reported that "the increased heart risks seen in the Avandia/Actos

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[14] The additional facts regarding the Buse situation further support Plaintiffs' allegations that Glaxo was aware of the link between Avandia and an increased risk of heart attack before and during the Class Period and that the Company was attempting to conceal that material fact from the public and investors.

[15] Lorraine L. Lipscombe, MD, *et al*., Thiazolidinediones and Cardiovascular Outcomes in Older Patients With Diabetes, The Journal of the American Medical Association, Dec. 12, 2007. (Attached hereto as Exhibit C.)

group were predominantly in those on Avandia."[16]

- On December 12, 2007, *The New York Times* published an article which reaffirmed previous studies' findings that "Avandia had significant elevated risks of heart attack and death." Indeed, *The New York Times* stated: "The new study concludes that Avandia users had a 60 percent increased risk of heart failure, a 40 percent increased risk of heart attacks and a 30 percent increased risk of death compared with patients taking other oral diabetes medicines." The article added that "the study's conclusions mirror those observed last May in an analysis published by Dr. Steven E. Nissen and colleagues from the Cleveland Clinic."[17]

- In an article dated December 11, 2007, *Reuters* reported that "[a]nother study has found evidence that certain diabetes drugs, especially GlaxoSmithKline's Avandia, can cause heart attacks and death . . ." and that the drug was linked to a statistically significant "40 percent higher risk of heart attack."[18]

III. ARGUMENT

A. Legal Standard on a Motion to Dismiss

Defendants have a heavy burden on this motion to dismiss, as they must demonstrate that the Plaintiffs either failed to state claims as a matter of law under Rule 12(b)(6) or did not properly plead those claims under the Federal Rules of Civil Procedure or the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. §78u-4, *et seq.*

In reviewing a motion to dismiss, the Court must presume that the allegations of the AC are true, read the AC as a whole, and give Plaintiffs the benefit of every favorable inference that can be drawn from its allegations. *See Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974); *see also Caiola v. Citibank, N.A.*, 295 F.3d 312 (2d Cir. 2002); *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 161 (2d

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[16] Rita Rubin, Latest study of diabetes drug Avandia reaffirms heart risk; 'Black box' warning may not go far enough, USA Today, Dec. 12, 2007. (Attached hereto as Exhibit D.)

[17] Stephanie Saul, Another Study Finds Diabetes Drug is Risky for Elderly, The New York Times, Dec. 12, 2007. (Attached hereto as Exhibit E.)

[18] Glaxo diabetes drug raises heart risk in study, Reuters, Dec. 11, 2007. (Attached hereto as Exhibit F.)

Cir. 2000); *In re Mercator Software, Inc.*, 161 F. Supp. 2d 143, 150 (D. Conn. 2001) (noting that all allegations must be read in their totality, not in isolation). The PSLRA "do[es] ***not*** change the standard of review for a motion to dismiss." *In re Initial Pub. Offering Sec. Litig.*, 241 F. Supp. 2d 281, 332 (S.D.N.Y. 2003) ("*IPO I*") (emphasis added); *Novak v. Kasaks*, 216 F.3d 300, 309-11 (2d Cir. 2000). Furthermore, a complaint "attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations," but rather must simply provide the grounds of entitlement to relief and raise a right to relief above the speculative level. *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1959 (2007) (citations omitted). As detailed below, the AC easily meets this standard.

B. Defendants' Positive Statements About Avandia Created a Duty to Disclose the Internal Studies Indicating that Use of Avandia Causes Increased Risk of Heart Attack

As detailed in the AC, Defendants repeatedly issued positive statements about Avandia, the results of clinical testing of Avandia and Avandia's positive contribution to Glaxo's reported financial results, but failed to disclose the internal studies – the Meta-Analyses – linking the use of Avandia to the increased risk of heart attack. ¶¶55-63. Defendants' repeated positive statements about Avandia created a duty to disclose material facts regarding Avandia and, in particular, the internal studies linking Avandia to a potential safety issue. *See SEC v. Tex. Gulf Sulphur Co.*, 401 F.2d 833, 962 (2d Cir. 1968) (holding that where a defendant voluntarily chooses to make a statement that is reasonably calculated to influence the investing public, defendant has a duty to disclose sufficient information so that the statement is not "so incomplete as to mislead"); *Ottmann v. Hanger Orthopedic Group, Inc.*, 353 F.3d 338, 352 (4th Cir. 2003) (finding that defendants' positive statements about the integration of two businesses created a duty to disclose that the combined company was experiencing a loss of referral business).

Generally, "once corporate officers undertake to make statements, they are obligated to speak truthfully and to make such additional disclosures as are necessary to avoid rendering the statements

made misleading." *In re Par Pharm., Inc. Sec. Litig.*, 733 F. Supp. 668, 675 (S.D.N.Y. 1990). In this regard, "the lack of an independent duty to speak in the first instance becomes irrelevant once a party chooses to discuss material issues, because upon choosing to speak one 'has a duty to be both accurate and complete.'" *Lapin v. Goldman Sachs Group, Inc.*, 506 F. Supp. 2d 221, 237 (S.D.N.Y., 2006) (quoting *Caiola*, 295 F.3d at 331); *see also In re Sotheby's Holdings, Inc. Sec. Litig.*, No. 00 Civ. 1041 (DLC), 2000 U.S. Dist. LEXIS 12504, at *12 (S.D.N.Y. Aug. 31, 2000); *United Paperworkers Int'l Union v. Int'l Paper Co.*, 801 F. Supp. 1134, 1143 (S.D.N.Y. 1992), *aff'd, mod. on other grounds*, 985 F.2d 1190 (2d Cir. 1993). Moreover, as this Court has held, "there is a 'duty to update' prior public statements that may have been true when originally made, but subsequently have become misleading as the result of intervening events." *In re Regeneron Pharms. Sec. Litig.*, No. 94 Civ. 1785 (CLB), 1995 U.S. Dist. LEXIS 4023, at *6-*7 (S.D.N.Y. Mar. 10, 1995) (finding that where defendants made positive statements about a drug, defendants were required to disclose data indicating the contrary even when derived from interim studies) (quoting *In re Time Warner, Inc. Sec. Litig.*, 9 F.3d 259, 267 (2d Cir. 1993)).

This Court's decision in *In re Regeneron* is particularly instructive. In *In re Regeneron*, defendants argued that they did not issue any "affirmative statements" and, therefore, had no duty to disclose interim data concerning a drug trial. 1995 U.S. Dist. LEXIS 4023, at *7. The Court rejected defendants' contentions, holding that once defendants chose to make public statements regarding the drug, they had a duty to do so in a "complete and accurate" manner. *Id*. The Court reasoned that complete and accurate disclosures were necessary because a "reasonable investor could infer," from defendants' chosen statements, that the company was "not facing difficulties with the progress of the drug," when, in fact, that was not entirely accurate. *Id*. at *7-*9.

Here, as alleged in the AC, Defendants made numerous statements regarding the efficacy and

safety of Avandia. For example, Defendants used the DREAM and ADOPT studies to highlight the safety and efficacy of the drug. ¶¶55-56, 58, 60, 62. Defendants also claimed that the drug was ***and would continue to be*** a key growth driver for the Company. ¶¶42, 44, 46-47, 49, 51, 53. When Defendants made these disclosures, however, they had a duty to do so in a complete and accurate manner. They also assumed a duty to make such *additional* disclosures as necessary in order to make those statements not misleading, in light of information later obtained or subsequent events. *See In re Regeneron*, 1995 U.S. Dist. LEXIS 4023, at *6-*7 (citing *In re Time Warner*, 9 F.3d at 268). In direct contravention of these duties, Defendants failed to inform investors that their own Meta-Analyses showed a risk of heart attacks by users of Avandia. ¶¶24-26, 43, 45, 48, 50, 52, 54, 57, 61, 63. Defendants likewise failed to inform investors of the potentially negative impact that the side-effect of heart attack could have on the sustainability of the profits and growth derived from Avandia. ¶¶50, 52, 54, 57, 61, 63. This is actionable under the federal securities laws. *See In re Forest Labs Sec. Litig.*, No. 05 Civ. 2827 (RMB), Slip. op. (S.D.N.Y. July 19, 2006) (attached hereto as Exhibit G) (holding that publishing favorable clinical data while concealing unfavorable data was actionable under the federal securities law and denying defendants' motion to dismiss in this regard); *In re NeoPharm, Inc. Sec. Litig.*, No. 02 C 2976, 2003 U.S. Dist. LEXIS 1862 (N.D. Ill. Feb. 7, 2003) (denying motion to dismiss and holding that positive statements about Phase I trials were materially misleading when defendants knew at the time that Phase II trials had already failed).

Moreover, the fact that Defendants' statements may have arguably been literally true is no defense to liability, as "the disclosure required by the securities laws is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead prospective buyers." *See McMahan & Co. v. Wherehouse Entm't, Inc.*, 900 F.2d 576, 579-80 (2d Cir. 1990) (citing *Greenapple v. Detroit Edison Co.*, 618 F.2d 198, 205 (2d Cir. 1980)).

Defendants argue that Glaxo was not required to disclose the Meta-Analyses because, in their view, the Meta-Analyses did not call the future viability of Avandia into "jeopardy"[19] and, according to Defendants, pharmaceutical companies are "under no duty to disclose safety data regarding a product until there is a reason to believe that the future viability of the product is jeopardized." Def. Mem. at 35-41. Defendants' argument is predicated on a misreading of *Carter-Wallace I* and *Bayer*.

In *Carter-Wallace I*, the Second Circuit held that *Carter-Wallace* was not required to disclose adverse safety reports about their drug felbatol because the reports did not provide a "statistically significant" link between felbatol and the "ill effects." 150 F.3d at 157. In other words, in *Carter-Wallace I*, Defendants had no reason to know that there was any connection between adverse effects reports and the use of felbatol until there was a link made. Under those circumstances, it is easy to understand why the Second Circuit would hold that an issuer does not have to disclose the receipt of adverse event reports. By contrast in this case, Glaxo itself conducted analyses that concluded that there was a statistically significant link between use of Avandia and the risk of heart attack – this is not simply the receipt of adverse event reports. *See* ¶¶24-26.

Following *Carter-Wallace I*, the Court in *In re Bayer* substantially denied a motion to dismiss and narrowly read the holding of *Carter-Wallace I*, explicitly rejecting the position taken by

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[19] Throughout their memorandum, Defendants take pains to argue that the Meta-Analyses were not meaningful studies and therefore were not significant. *See, e.g.*, Def. Mem. at 39. Aside from the fact that this is inappropriate factual disputation, it is also patently absurd. Clearly, meta-analysis is a meaningful form of study, as the Defendants performed two separate meta-analyses on Avandia and it was the disclosure of another meta-analysis (Dr. Nissen's) that, in part, caused the decline in the price of Glaxo securities. Finally, to the extent that Defendants rely on statements from the testimony of the FDA commissioner to support their position on meta-analysis, *e.g.*, Def. Mem. at 17, those statements have to be taken in context. The FDA has come under fire for failing to quickly respond to information concerning drug safety. Under these circumstances, one can understand why the FDA would be downplaying the significance of the Meta-Analyses, which they sat on for eighteen months.

Defendants here. In this regard, the Court in *In re Bayer* stated that "[t]he *Carter-Wallace* decisions do not hold that adverse event reports are always immaterial. Indeed, the Second Circuit has instructed district judges that materiality is a flexible, fact-based determination." 2004 WL 2190357, at *9**.** Further, the Court held that "*Carter-Wallace* stands for the proposition that isolated adverse event reports, lacking statistical significance, do not prove that a drug is unsafe" and further noted that *Carter-Wallace* does not preclude a finding that "adverse event reports, coupled with other evidence, can put a pharmaceutical company on notice concerning a drug's safety risks." *Id.*; *see also In re Corning Sec. Litig.*, No. 92 Civ. 345 (TPG) 2001 U.S. Dist. LEXIS 12912, at *4 (S.D.N.Y. Aug. 27, 2001) (rejecting argument that *Carter-Wallace I* created a "bright-line" pleading standard). Finally, the plaintiffs in *In re Bayer* argued that Defendants' duty to disclose the safety issues with the drug derived from "adverse event reports" and the Court discounted the significance of adverse event reports.

Here, the allegations are much more than the receipt of adverse event reports. The AC alleges that Glaxo had conducted internal studies – the Meta-Analyses – which linked the use of Avandia to an increased risk of heart attack. ¶¶24-26. The Meta-Analyses were comprised of 42 separate, double-blinded, randomized, controlled clinical trials and were not simply based on the receipt of adverse event reports. In addition, Defendants have acknowledged their awareness of the increased risk of heart attacks associated with Avandia,[20] yet chose not to warn Avandia's users of the drug's medical dangers and chose not to inform Glaxo's investors of the existence of negative findings from the Company's own Meta-Analyses. These facts further distinguish this case from

[20] *See, supra,* at 5-6.

Carter-Wallace I.[21]

At bottom, Defendants' issuance of positive statements about Avandia created a duty to disclose the then-known adverse conclusions of the Meta-Analyses. Defendants failed to do so and may be held liable under the securities laws for their omission.

C. The AC Alleges Facts Giving Rise to a Strong Inference of Scienter

1. The *Tellabs* Decision

In *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499 (2007), the United States Supreme Court articulated the standard that courts must now apply in determining whether a plaintiff has pleaded a "strong inference of scienter," as required by the Private Securities Litigation Reform Act of 1995 ("PSLRA"). The Supreme Court established the following prescriptions:

> First, faced with a Rule 12(b) motion to dismiss a §10(b) action, courts must, as with any motion to dismiss for failure to plead a claim on which relief can be granted, accept all factual allegations in the complaint as true. . . . Second, courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss. . . . Third, in determining

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[21] In *In re Alliance Pharm. Corp. Sec. Litig.*, 279 F. Supp.2d 171 (S.D.N.Y. 2003), defendants' concern about the viability of their drug was only one of several factors discussed by the Court as part of its determination as to whether to grant summary judgment to defendants in connection with plaintiff's Section 11 claim. *Id.* at 189-90. And, more importantly, the Court did not need to reach that determination, as it considered defendants' statement to be true on its face. Specifically, the Court stated:

> The [allegedly false] statement at issue contains no report on the results of the ongoing cardiac clinical trial that could be rendered misleading without reports of continuing developments. All it says is that Oxygent is currently being evaluated. That statement was absolutely and indisputably correct . . . There is no evidence in the record that there was any plan, or any need, to end the evaluation of Oxygent at that time, or even to alter the circumstances under which it was being evaluated. And there is no evidence that defendants had reason to be concerned about the viability of the drug.

Id. at 49-51. Clearly, the holding in *In re Alliance* is inapposite to facts at issue before this Court.

> whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing inferences.

Id. at *5-*6. In determining the adequacy of scienter, the Court reiterated that "the court's job is not to scrutinize each allegation in isolation but to assess all the allegations holistically." *Id.* at *7. Considering each of these factors, the Court adopted the following standard, "[w]hen the allegations are accepted as true and taken collectively, would a reasonable person deem the inference of scienter at least as strong as any opposing inference?" *Id.* at *32-*33. Furthermore, the Court refused to adopt the more stringent standard supported by defendants, holding instead that the "inference that the defendants acted with scienter need not be irrefutable . . . or even the 'most plausible of competing interests.'" *Id.* at *29 (internal quotation and citations omitted).[22]

While the Second Circuit has equated its "strong inference" requirement under Rule 9(b) with that contained in the PSLRA, *see, e.g.*, *Novak*, 216 F.3d at 309-10, it has not addressed the issue of the impact that the PSLRA or Rule 9(b) have on the inferences permissible on a motion to dismiss. However, the Second Circuit has never proscribed the evaluation of competing inferences of scienter as an improper usurpation of the jury's role. The *Tellabs* decision, therefore, will have little practical effect on the determination of scienter in Second Circuit cases. *See ATSI Commc'ns., Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2nd Cir., 2007) (holding that scienter was plead by showing either motive and opportunity or circumstantial evidence of recklessness and that to determine "an inference of scienter to be 'strong, a reasonable person [must] deem [it] cogent and at

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[22] "Seizing on the 'at least as likely' language, courts since *Tellabs* have concluded that even if the plaintiff demonstrates only that an inference of scienter is at least as compelling as any nonculpable explanation for the defendant's conduct, the 'tie . . . goes to the plaintiff.'" *In re Top Tankers, Inc.*, No. 06 Civ. 13761 (CM), 2007 U.S. Dist. LEXIS 94259 (S.D.N.Y., Dec. 18, 2007) *quoting Sloman v. Presstek, Inc.*, No. 06-cv-377-JD, 2007 U.S. Dist. LEXIS 69475, at *24-*25 (D.N.H. Sept. 18, 2007).

least as compelling as any opposing inference that can be drawn from the facts alleged.'") (citing *Tellabs*, 127 S. Ct. 2499).

As part of their overall analysis of the Supreme Court's decision in *Tellabs*, Defendants argue that when a court analyzes the PSLRA scienter pleading requirement, it must accept all the factual allegations in the complaint as true and that this application pertains to "non-conclusory allegations based on personal knowledge." Def. Mem. at 43. This is simply not the proper legal standard and is a blatant mischaracterization of the *Tellabs* holding, including the majority, concurring and dissenting opinions. The Supreme Court did not say that the acceptance of all the factual allegations applies only to non-conclusory allegations based on personal knowledge.

Rather, the facts of the complaint must be accepted as true, through an examination of the complaint in its entirely, for the purposes of ascertaining a strong inference of scienter. But, by no means does the prescribed examination established in *Tellabs* need to be applied to non-conclusory allegations based on personal knowledge. *See Tellabs*, 127 S. Ct. 2499; *cf. In re Top Tankers*, 2007 U.S. Dist. LEXIS 94259, at *17 (quoting *Tellabs* as emphasis "that all the facts alleged, taken collectively, must be considered in deciding whether the pleading gives rise to a strong inference of scienter."); *In re Group Sec. Litig.*, No. 06 Civ. 5853 (SAS), 2007 U.S. Dist. LEXIS 81565 (S.D.N.Y. Nov. 2, 2007) (stating that, in *Tellabs*, "the Court held that in order to determine whether scienter is adequately plead, courts must look at the complaint as a whole"); *In re Xethanol Corp. Sec. Litig.*, No. 06 Civ. 10234 (HB) 2007 U.S. Dist. LEXIS 65935 (S.D.N.Y., Sept. 7, 2007) (noting that, per *Tellabs*, all factual allegations in the complaint are taken as true and the complaint is weighed in its entirety); *see also Ernesto Darquea v. Jarden Corp.*, No. 7:06-cv-00722-CLB, 2007 U.S. Dist. LEXIS 65739, at *6 (S.D.N.Y. Sept. 5, 2007) (motion for reconsideration by defendants denied) (stating that "the Court is constrained to accept the Plaintiffs' version of the facts as true and

to conclude that on the whole, the inference of scienter is as compelling as an opposing inference, notwithstanding what inferences might be better drawn from a more developed record.").

Here, when the AC is considered in its entirety, it is clear that the AC alleges a strong inference that Defendants acted with scienter.

2. The AC Sufficiently Alleges Facts Demonstrating Conscious Misbehavior or Recklessness

Plaintiffs have sufficiently pled that Defendants' misrepresentations were knowing or, at a very minimum, reckless. Defendants cannot deny that they were aware of the Meta-Analyses and the conclusion that the use of Avandia was linked to an increase risk of heart attack. ¶¶34-35.[23] Given their knowledge of the findings of the Meta-Analyses, Defendants were reckless in issuing numerous positive statements about Avandia without disclosing the known link to heart attack. Indeed, this is classic evidence of recklessness.

Courts have generally held that conscious misbehavior constitutes conduct "which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *In re Nortel Networks Corp. Sec. Litig.*, 238 F. Supp. 2d, 613, 631 (S.D.N.Y. 2003). Further, "securities fraud claims typically have sufficed to state a claim based on recklessness when they have specifically alleged defendants' knowledge of facts or access to information contradicting their public statements." *Novak*, 216 F.3d at 308 (holding that a complaint pleads recklessness where it alleges that "defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation.").

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[23] It has now been revealed that Defendants went to great lengths to suppress additional pre-Class Period findings that demonstrated the risk of heart attacks that users of Avandia were subject to. *See, supra*, at 8-10.

In light of this criterion, where a corporation's "high-level executive officer" makes public statements that are contradicted by facts that are available when the statements are made, an inference arises that the officer "had intimate knowledge of those facts or should have known them." *In re Atlas Air Worldwide Holdings, Inc. Sec. Litig.*, 324 F. Supp. 2d 474, 489 (S.D.N.Y. 2004). In fact, "even in the absence of specific information contradicting their public statements," knowledge of the contradictory information will be imputed to individual defendants where the statements concern matters that are "sufficiently significant" to the company. *In re eSpeed, Inc. Sec. Litig.*, 457 F. Supp.2d 266, 293 (S.D.N.Y. 2006); *see also In re Winstar Communications*, No. 01 CV 3014 (GBD), 2006 U.S. Dist. LEXIS 7618, at *22 (S.D.N.Y. Feb. 27, 2006) (imputing scienter to key officers who filed false financial statements).

Here, the Individual Defendants were high-level executives who had access to undisclosed information regarding Avandia, and thus knew that Glaxo's business would suffer when the public learned of the direct association between Avandia and its link to increased risk of heart attacks. Moreover, the AC alleges, and Defendants do not deny, that they had access to studies or reports that evinced the risk of heart attack to Avandia users. Accordingly, the AC has sufficiently alleged "defendants' knowledge of facts or access to information contradicting their public statements." *Novak*, 216 F.3d at 308; *see also In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 76-77 (2d Cir. 2001) (finding allegations as to what defendants actually knew, "while at the same time making public statements that painted a different picture," to be "consistent with recklessness.").

Further, Avandia was a vital component of Glaxo's overall business. ¶22. In fact, Defendants repeatedly referred to Avandia as one of the Company's key products and Avandia was one the Company's best-selling drugs. ¶¶42, 46, 49, 51, 62. In similar situations, courts have imputed knowledge concerning developments affecting a company's core operations to an officer,

director or other high-level executive merely by virtue of his position within the company. *See, e.g.*, *Cosmas v. Hassett*, 886 F.2d 8,13 (2d Cir. 1989) (holding that directors are imputed with knowledge of the removal of a "potentially significant source of income for the company"); *In re Atlas Air*, 324 F. Supp. 2d at 491 (finding scienter where high-level executive officers should have known about the impairment in value of inventory, but approved misleading financial statements anyway); *In re Xerox Corp. Sec. Litig.*, 165 F. Supp. 2d 208, 223 (D. Conn. 2001) (imputing awareness of the adverse effects of a company's restructuring to three executive officers of the company).

Defendants argue that Plaintiffs' allegation of recklessness "make no sense" because "the Complaint does not contain a single factual allegation suggesting that any of the Individual Defendants or anyone else at GSK considered Avandia dangerous based on the meta-analysis results or any other data." Def. Mem. at 44-45. This argument fails because it ignores the AC's allegations that Defendants have admitted that they knew of the findings of the Meta-Analyses and that they believed that they could have done more to advise the public. *See* ¶35. Whether the Defendants believed that their conduct was appropriate is a factual issue that is not appropriate on this motion and is not required to be examined under *Tellabs*. Besides, the issue is not whether Avandia is dangerous, but whether Defendants knew about the potential safety issue – which they undoubtedly did.[24]

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[24] Defendants' knowledge of the link between Avandia and the risk of heart attack is what distinguishes this case from *In re Carter-Wallace Sec. Litig.*, 220 F.3d 36, 38, 41-42 (2d Cir. 2000) ("*Carter-Wallace II*"). In *Carter-Wallace II*, the Second Circuit held that plaintiffs had failed to plead scienter because they were unable to allege that defendants had knowledge of the link between felbatol and certain adverse event reports and that given the nature of the reports, defendants would have no reason to know of the link. By contrast here, Defendants have admitted that they knew of the link. It was Defendants' own study and findings, in fact, that confirmed the link.

Similarly, Defendants' highlighting of the fact that the raw data from the Meta-Analyses was on Glaxo's website at some point borders on being meaningless. Def. Mem. at 17, 22. It was raw data that would be virtually indecipherable to anyone viewing it. Under such circumstances, it can hardly be characterized as a "disclosure" of the Meta-Analyses. Defendants would surely know that anyone viewing the Meta-Analyses on the Company's website would not learn of the increased risk of heart attack associated with the use of Avandia.

Finally, given the new facts concerning the Congressional investigation, Defendants are hard pressed to argue that they were not trying to conceal known safety risks from the public and investors. As the report indicates, Glaxo engaged in a campaign designed to quiet Dr. Buse and silence his criticisms of Avandia and the drug's potential link to heart attack. This conduct certainly supports a strong inference that Defendants were aware of the known risk and its concealment from the public.

3. The AC Sufficiently Alleges Facts Which Demonstrate Motive and Opportunity

Further supporting the strong inference of scienter, Plaintiffs have adequately pled Defendants' "motive and opportunity" for committing fraud. As high-ranking corporate officers, each Individual Defendant's opportunity for fraud is unequivocal. *In re Scholastic*, 252 F.3d at 74 (summarily noting that corporate officers "ha[ve] access to insider information and thus ha[ve] an opportunity to commit fraudulent acts"). Indeed, Defendants do not dispute that they had an opportunity to commit the fraud or that the AC alleges that they did. *See In re Time Warner*, 9 F.3d at 269 ("[N]o one doubts that the defendants had the opportunity, if they wished, to manipulate the price of [the company's] stock").[25]

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[25] Instead, Defendants claim that the AC does not allege motive. *See* Def. Mem. at 48.

However, the AC more than adequately pleads Defendants' motive to commit the fraud. Specifically, it describes in great detail their plan to artificially inflate Glaxo's stock price in order to enable the Individual Defendants to sell-off approximately $27.5 million of their personal holdings in the Company.

(i) The Individual Defendants' Stock Sales Establish Motive

Stock sales by insiders generally imply a strong inference of scienter when those sales are "unusual." *In re Scholastic*, 252 F.3d at 74; *see also In re Atlas Air*, 324 F. Supp. 2d at 488 ("Typically, the pleading of motive and opportunity is sufficient when a plaintiff alleges that corporate insiders made materially misleading statements while selling large amounts of stock at artificially high prices."). A court will generally consider several factors to determine whether insider trading activity is unusual, including "the amount of profit from the sales, the portion of the stockholdings sold, the change in volume of insider sales, and the number of insiders selling." *In re Scholastic*, 252 F.3d at 74-75 (citing *Rothman v. Gregor*, 220 F.3d 81, 94 (2d Cir. 2000)). A court will also consider the timing of the sales. *In re Oxford Health Plans, Inc. Sec. Litig.*, 187 F.R.D. 133, 139 (S.D.N.Y. 1999) ("*Oxford*") (holding that "[t]rades made a short time before a negative public announcement are suspiciously timed").[26]

Here, the Company's highest-level executives collectively sold approximately $27.5 million worth of their personal holdings in the Company at suspicious times. It is noteworthy that more than $13 million of the overall sales alleged in the AC took place just prior to the close of the Class Period. ¶70.

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[26] Moreover, as this Court recognized in *Oxford*, "[a]lthough plaintiffs generally use evidence of unusual or suspicious insider trades to provide evidence of motive, it is also relevant as evidence of conscious or reckless behavior." 187 F.R.D. at 140 n.1.

In *Oxford*, this Court held that stock sales were suspicious where certain insiders separately sold between $621,000 and $5.4 million worth of stock (and others sold more). 187 F.R.D. at 140. Other courts made similar findings when presented with even lesser sales. *See IPO I*, 241 F. Supp. 2d at 365-66 (insider sold "hundreds of thousands of dollars worth of inflated stock"); *In re MTC Elec. Techs. S'holders Litig.*, 898 F. Supp. 974, 980 (E.D.N.Y. 1995) (defendant sold almost 8,000 shares for profits of $173,000); *see also Rubinstein v. Collins*, 20 F.3d 160, 169 (5th Cir. 1994) (collective sales of only $760,599).[27]

Therefore, based on the size of the insider trading (approximately $27.5 million) and the fact

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[27] Defendants attempt to shield their motive by clouding the nature of their trades. Defendants' desperate contentions range from the fact that certain insiders may have technically increased their holdings during the Class Period, perhaps through awarded options (Def. Mem. at 48, 52 and 54), that not all Individual Defendants allegedly participated in the improper insider trading (Def. Mem. at 49), that some alleged sales were by non-defendants (Def. Mem. at 50), that a select number of insider sales were not conducted in close proximity to the alleged misstatements (Def. Mem. at 52), or that for certain insiders, only a percentage of their shares were sold as part of the insider trading (Def. Mem. at 54).

Defendants' medley of assertions, however, have no bearing on the instant motion. As this Court has recognized, the mere fact that Defendants profited from the sale of some of their stock, as opposed to all of it, still means that they obtained a concrete benefit from the artificially inflated stock price. *See Oxford*, 187 F.R.D. at 140 (retention of a large position after realizing profit from stock sales does not vitiate insider trading liability); *see also In re MicroStrategy, Inc. Sec. Litig.*, 115 F. Supp. 2d 620, 647 (E.D. Va. 2000) (refusing to hold that insider sales did not create an inference of scienter simply because defendants sold less than 5% of their shares); *cf. Stevelman v. Alias Research Inc.*, 174 F.3d 79, 82, 85-86 (2d Cir. 1999) (insider sales sufficient to establish motive even in absence of allegation as to percentage of shares retained). Moreover, Defendants' characterization of the number of shares they held after their trades improperly raises a contested factual issue. *See In re Scholastic*, 252 F.3d at 75 (contested issues concerning the percentage of shares held cannot be resolved on a Rule 12(b)(6) motion). Likewise, the fact that the Individual Defendants claim to have sold their stock pursuant to a trading plan does not negate an inference of scienter, but instead prematurely raises an affirmative defense that is inappropriate on this motion. *See* 17 C.F.R. §240.10b5-1(c) (setting forth the affirmative defense); *see also In re Cardinal Health, Inc. Sec. Litig.*, 426 F. Supp. 2d 688, 734 (S.D. Ohio 2006) ("As it is typically premature to raise affirmative defenses in a motion to dismiss, this Court will not consider the impact of [defendant]'s purported 10b5-1 trading plan at this stage of the pleadings.").

that nearly one-half of that amount was generated from sales that took place at the very end of the Class Period, the AC's allegations of motive are clearly adequate.

D. Defendants' Actionable Statements Are Not Protected by the Bespeaks Caution Doctrine or the "Safe Harbor" Provision of the PSLRA

Assuming *arguendo* that some of the statements that Defendants made are forward-looking in nature, those statements are not protected by the bespeaks caution doctrine or the PSLRA's safe harbor provision because, as demonstrated above, Defendants knew that the statements were false and misleading at the time they were made. *See In re IBM Corporate Sec. Litig.*, 163 F.3d 102, 107 (2d Cir. 1998) (holding that "[s]tatements regarding projections of future performance may be actionable under Section 10(b) or Rule 10b-5 if they are worded as guarantees or are supported by specific statements of facts . . . or if the speaker does not genuinely or reasonably believe them"); *In re AOL Time Warner, Inc. Sec. & "ERISA" Litig.*, 381 F. Supp. 2d 192, 223 (S.D.N.Y. 2004) (holding that "no degree of cautionary language will protect material misrepresentations or omissions where defendants knew their statements were false when made"); *see also Oxford*, 187 F.R.D. at 141 (holding that statements may be actionable if they are made without any basis or if "the speakers were aware of any facts undermining the accuracy of these statements").

A warning that fails to disclose specific known facts is insufficiently precise and will not insulate Defendants' statements from liability pursuant to the bespeaks caution doctrine. *See, e.g., In re Am. Express Co. Sec. Litig.*, No. 02 Civ. 5533 (WHP), 2004 U.S. Dist. LEXIS 5497 (S.D.N.Y. Mar. 31, 2004); *In re Regeneron Pharms., Inc. Sec. Litig.*, No. 03 Civ. 3111 (RWS) 2005 U.S. Dist. LEXIS 1350 (S.D.N.Y. Feb. 3, 2005) (finding that "the safe harbor provision does not protect a statement made with 'actual knowledge' that it was false and misleading"); *see also* 15 U.S.C. §78u-5(c)(1)(B).

Here, as alleged, Defendants were already in possession of concrete data and findings

showing that Avandia caused an increased risk of heart attacks at the time they issued the false and misleading statements.

Further, the statements were not "accompanied by ***meaningful*** cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C. §78u-5 (emphasis added.); *see also Irvine v. ImClone Sys., Inc.*, No. 02 Civ. 109 (RO), 2003 U.S. Dist. LEXIS 9342, at *4 (S.D.N.Y. June 4, 2003) (finding generic cautionary language to be insufficient); *In re Vivendi Universal, S.A. Sec. Litig.*, 381 F. Supp. 2d 158, 183 (S.D.N.Y. 2003) (emphasizing that cautionary language must "render reliance on the misrepresentation unreasonable"). The purported language must "precisely address the substance of the specific statement or omission that is challenged." *See In re Nortel*, 238 F. Supp. 2d at 628. Here, Defendants allude to mere boilerplate warnings that are insufficient to bring the statements within the protection of the safe harbor provision. *See Irvine*, 2003 U.S. Dist. LEXIS 9342, at *4 (repeated general warnings did not constitute sufficient cautionary language). For example, Defendants rely on the following statements: (a) "actual results to differ materially from expected and historical results"; (b) "some products may 'have only limited commercial success as a result of efficacy or safety concerns . . .'"; and (c) "when drugs and vaccines are introduced into the marketplace, unanticipated side effects may become evident." Def. Mem. at 58. These statements cannot be considered "meaningful cautionary statements" as contemplated by 15 U.S.C. §78u-5. *See Ruskin v. TIG Holdings, Inc.*, No. 98 Civ. 1068 (LLS), 2000 U.S. Dist. LEXIS 11517, at *17-*19 (S.D.N.Y. Aug. 14, 2000). The statements have no bearing on this matter and provide no rationale as to why Defendants chose not to disclose the findings of the Meta-Analyses. At best, "unanticipated side effects may become evident" can be construed as a cautionary statement. Here, however, heart attack was not an unanticipated side-effect of Avandia. Rather, it was a side-effect

that Defendants knew was associated with Avandia.

Further, even assuming (without conceding) that adequate cautionary language accompanied certain of the statements, "it is well recognized that even when an allegedly false statement has both a forward-looking aspect and an aspect that encompasses a representation of present fact, the safe harbor provision of the PSLRA does not apply." *In re Nortel*, 238 F. Supp. 2d at 629 (quoting *In re APAC Teleservices, Inc. Sec. Litig.*, No. 97 Civ. 9145 (BSJ), 1999 U.S. Dist. LEXIS 17908, at *7 (S.D.N.Y. Nov. 19, 1999)). Further, "linking future success to present and past performance does not render statements immune from liability." *APAC*, 1999 U.S. Dist. LEXIS 17908, at *8.

IV. CONCLUSION

For the reasons set forth herein, Plaintiffs respectfully request this Court to deny Defendants' motion to dismiss in its entirety.[28]

DATED: January 14, 2008

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[28] In the event that the Court deems the claims against Defendants are insufficiently pled, however, Plaintiffs request the Court to grant leave to replead pursuant to Fed. R. Civ. P. 15, particularly in light of the additional information that became available after the AC was filed relating to Defendants' knowledge (prior to and during the Class Period) of the statistical significance of the risk of heart attacks that was linked to Avandia.

CERTIFICATE OF SERVICE

I, Samuel H. Rudman, hereby certify that on January 14, 2008, I caused a true and correct copy of the attached:

> Memorandum of Law in Opposition to Defendants' Motion to Dismiss the Amended Complaint

to be served: (i) electronically on all counsel registered for electronic service for this case; and (ii) by first-class mail to any additional counsel.

/s/ Samuel H. Rudman
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GLAXOSMITHKLINE 07

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